

Serial No. 10/748,003  
Response to Office Action

**In the Claims**

Please amend the claims as indicated below. This version of the pending claims will replace all prior versions.

1. (currently amended) A method of inhibiting the growth of gastrointestinal tumors comprising the steps of orally administering to an individual with one or more gastrointestinal tumors, a formulation comprising:

- a) polymeric microspheres encapsulating a drug composition comprising sulindac and polymeric microspheres encapsulating a drug composition comprising IL-12; or
- b) polymeric microspheres encapsulating a drug composition comprising sulindac and IL-12;

wherein said oral administration of the encapsulated sulindac and IL-12 has a greater effect on ~~is synergistically effective in~~ inhibiting the growth of the one or more gastrointestinal tumors than sulindac or IL-12 alone.

2. (previously presented) The method of claim 1, wherein the polymer of the polymeric microspheres is a polyanhydride.

3. (original) The method of claim 1, wherein the polyanhydride is selected from the group consisting of polylactic acid, polylactide-co-glycolide, polycaprolactone and poly(fumaric-co-sebacic anhydride).

4. (original) The method of claim 1, wherein the polymeric microspheres are prepared by the phase inversion method.

5. (original) The method of claim 1, wherein the polymeric microspheres are prepared by the hot melt method.

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6. (original) The method of claim 1, wherein the amount of sulindac administered is about 100-400 mg/dose.

7. (original) The method of claim 1, wherein the amount of IL-12 administered is about 100-300 ng/kg.

8. (original) The method of claim 1, wherein the gastrointestinal tumor is a colorectal tumor.

9. (previously presented) The method of claim 1, wherein the polymer of the polymeric microspheres encapsulating the sulindac is polylactic acid or poly(fumaric-co-sebacic acid).

10. (previously presented) The method of claim 1, wherein the polymer of the polymeric microspheres encapsulating the IL-12 is polylactic acid.

11. (original) The method of claim 1, wherein the polymeric microspheres are administered to the individual in combination with a treatment selected from the group consisting of surgery, radiation, chemotherapy and immunotherapy.

12. (withdrawn) A method of preventing the development of gastrointestinal tumors comprising the steps of orally administering to an individual a formulation comprising polymeric microspheres encapsulating a drug composition comprising an agent selected from the group consisting of sulindac, IL-12 or a combination thereof, wherein said oral administration of the formulation is effective in preventing the development of gastrointestinal tumors.

13. (withdrawn) The method of claim 12, wherein the polymer of the polymeric microspheres comprises a polyanhydride.

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14. (withdrawn) The method of claim 13, wherein the polyanhydride is selected from the group consisting of polylactic acid, polylactide-co-glycolide, polycaprolactone and poly(fumaric-co-sebacic anhydride).

15. (withdrawn) The method of claim 12, wherein the polymeric microspheres are prepared by the phase inversion method.

16. (withdrawn) The method of claim 12, wherein the polymeric microspheres are prepared by the hot melt method.

17. (withdrawn) The method of claim 12, wherein the amount of sulindac administered is about 100-400 mg/dose.

18. (withdrawn) The method of claim 12, wherein the amount of IL-12 administered is about 100-300 ng/kg.

19. (withdrawn) The method of claim 12, wherein the gastrointestinal tumor is a colorectal tumor.

20. (withdrawn) The method of claim 12, wherein the polymer in the polymeric microspheres is polylactic acid or poly(fumaric-co-sebacic acid) and the encapsulated agent is sulindac.

21. (withdrawn) The method of claim 12, wherein the polymer in the polymeric microspheres is polylactic acid and the encapsulated agent is IL-12.

22. (withdrawn) The method of claim 12, the polymeric microspheres are administered in combination with a treatment selected from the group consisting of surgery, radiation, chemotherapy and immunotherapy.

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23. (withdrawn) A composition comprising polyanhydride microspheres, wherein the microspheres encapsulate an agent selected from the group consisting of sulindac, IL-12 or a combination thereof.
24. (withdrawn) The composition of claim 23, wherein the polyanhydride is selected from the group consisting of polylactic acid, polylactide-co-glycolide, polycaprolactone and poly(fumaric-co-sebacic anhydride).
25. (withdrawn) The composition of claim 24, wherein the polyanhydride is polylactic acid or poly (fumaric-co-sebacic acid) and the encapsulated agent is sulindac.
26. (withdrawn) The composition of claim 24, wherein the polyanhydride is polylactic acid and the encapsulated agent is IL-12.